APR 7 2005

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K050377

510(k) Summary of Safety and Effectiveness

In Accordance with SMDA of 1990

NBD Head Screw

January 21, 2005

Company:
NBD, LLC
605 Industrial Court
Woodstock, GA 30189

Trade Name:
NBD Head Screw

Common Name:
Head Screw

Product Code and Regulatory Classification:
HAW: 882.4560 Stereotaxic Instrument

Product Classification:
Class II

Intended Use:
The NBD Head Screws are an accessory that is intended to support the head frame in stereotactic procedures. The head frames are supported by either a three point-of-contact or four point-of-contact position depending on the frame design.

Device Description:

The NBD Head Screw is a single-use threaded clear anodized aluminum screw which is manufactured in lengths ranging from 33mm-57mm.

Performance Data:

No applicable performance standards have been promulgated under Section 514 of the Food, Drug, and Cosmetic Act for this device.

Substantial Equivalence:

The NBD Head Screw is similar in intended use, material, safety, and efficacy to the Elekta Stereotactic head screw accessory, K972324, as well as accessories currently in commercial distribution by Radionics and Leibinger, and Ohio Medical Instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2005

Mr. Tim B. Lusby
General Manager
New Business Development, LLC
605 Industrial Court
Woodstock, Georgia 30189

Re: K050377
Trade/Device Name: NBD Head Screw
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 25, 2005
Received: March 28, 2005

Dear Mr. Lusby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

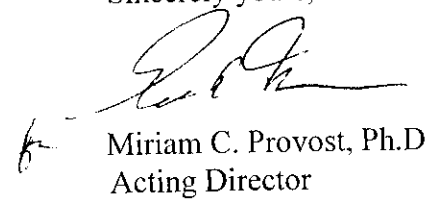
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K050377

Device Name: NBD Head Screw

Indications For Use: The NBD Head Screws are an accessory that is intended to support the head frame in stereotactic procedures. The head frames are supported by either a three point-of-contact or four point-of-contact position depending on the frame.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K050377